

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 875 222 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
31.07.2002 Bulletin 2002/31

(51) Int Cl.7: **A61F 13/02, A61F 13/15,
A61L 15/60**

(21) Application number: **98303433.1**

(22) Date of filing: **01.05.1998**

(54) **Absorbent wound dressings**

Absorbierende Wundverbände

Pansements absorbants pour plaies

(84) Designated Contracting States:
AT BE CH DE FR IE LI LU NL SE

(30) Priority: **02.05.1997 GB 9709024**

(43) Date of publication of application:
04.11.1998 Bulletin 1998/45

(73) Proprietor: **JOHNSON & JOHNSON MEDICAL,
INC.**
Arlington, Texas 76004-3030 (US)

(72) Inventor: **Addison, Deborah**
Near Clapham, Lancaster, LA2 2HB (GB)

(74) Representative: **Fisher, Adrian John et al**
CARPMAELS & RANSFORD
43 Bloomsbury Square
London WC1A 2RA (GB)

(56) References cited:
EP-A- 0 122 185 **US-A- 5 584 801**

EP 0 875 222 B1

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates to absorbent wound dressings for application to exuding wounds.

[0002] It is customary to apply absorbent wound dressings to wounds in order to absorb wound exudate as it is produced, whilst protecting the wound from airborne contamination. A drawback of conventional absorbent wound dressings is that they frequently contain absorbent fibrous materials, such as cotton lint, that shed fibers into the wound causing irritation and inhibiting wound healing. A further drawback of some conventional absorbent wound dressings is that they can be too effective, resulting in excessive dryness at the surface of the wound.

[0003] EP-B-0091800 and EP-B-0123465 describe surgical dressings in which the wound contacting layer is a so-called "intelligent" polymer film. These polymer films are continuous sheets of polymer that have much higher moisture vapour permeability when wet than when dry. The films allow the passage of moisture vapour at high rates when the film is wet, but allow much less moisture vapour to pass through when the film is dry, thereby preventing excessive drying out of the wound surface. These dressings suffer from the drawback that, even when wet, the continuous intelligent films have fairly low moisture permeability. This can result in pooling of exudate under the film in heavily exuding wounds.

[0004] GB-A-2175208 describes wound dressings that have reservoir compartments filled with absorbent material. The compartments communicate with the surface of the wound through slits in a wound contacting layer. These dressings are of relatively complex construction, and are not responsive to differing rates of flow of wound exudate.

[0005] JP-A-07100197 describes wound dressings consisting of a layer of fibrous absorbent material laminated to a wound contacting film. Slits are provided in the wound contacting film and extend through the absorbent layer to allow the passage of wound exudate into the absorbent layer. The film is alleged to prevent the fibers of the absorbent layer from contacting the wound site. There is no suggestion that such dressings could be made responsive to differing rates of flow of wound exudate.

[0006] EP-A-0099748 describes wound dressings comprising an absorbent layer and a wound contacting net that functions to reduce the tendency of the dressing to adhere to the wound, and retains loose threads or particles that may be present in the core absorbent material. It is stated that the net should be sufficiently elastically extensible to adjust to any dimensional changes in the absorbent layer. However, there is no suggestion that the dressing is responsive to the rate of flow of wound exudate.

[0007] US 5,584,801 discloses a wound covering comprising a film formed of a polyurethane resin, or a

lamine of the polyurethane film and an absorptive cloth, wherein the polyurethane film or the cloth contains an antibacterial agent, and perforations are formed at least on the polyurethane film. The polyurethane resin film is permeable to water vapour.

[0008] EP 0,122,085 describes a dressing comprising a film which consists of two layers laminated together, the first layer, which is the lesion contacting layer, is formed from a material which swells in contact with water. The second layer does not swell or swells less than the first layer when in contact with water. The film has apertures running through the two layers. When the first layer is placed in contact with a wet lesion the different swell characteristics causes the apertures to open allowing water to pass through the film from the wet surface to the top of the second layer. On a dry surface the apertures are closed.

[0009] It is an object of the present invention to provide an improved absorbent wound dressing that can be applied to exuding wounds, and that is responsive to the rate of wound exudate production so that excessive dryness of the wound surface is avoided when there is little exudate being produced, but pooling of exudate under the dressing is also avoided when there is heavy exudate production.

[0010] The present invention provides a wound dressing comprising a wound contacting sheet laminated to one side of an absorbent layer of water-swellaable absorbent material, a liquid water-impermeable backing layer is laminated to the other side of the absorbent layer, wherein the wound contacting sheet is provided with one or more slits therein, whereby swelling of the absorbent layer due to adsorption of wound exudate causes the wound contacting sheet to bulge, thereby opening up the slits to increase the liquid permeability of the wound contacting sheet, characterised in that the absorbent material is a polyurethane polymer foam such that the swelling of the absorbent layer is reversible.

[0011] In use, the exudate passes through the slits in the wound contacting sheet and into the absorbent layer. The absorbent layer swells as it absorbs the exudate, and the swelling of the wound contacting layer causes the absorbent layer and the contacting sheet laminated thereto to bulge, thereby opening the slits in the contacting sheet wider and allowing the passage of high flow rates of exudate. As the wound dries out, the absorbent layer also dries out and shrinks, causing the slits in the wound contacting sheet to close up so that the flow rate of exudate through the contacting sheet is reduced and excessive drying out of the wound surface is avoided.

[0012] Preferably, a plurality of slits is provided in the wound contacting layer, and more preferably the plurality of slits are preferably substantially parallel. Preferably, the slits do not extend into the absorbent layer, but are only present in the wound contacting sheet. Preferably, the wound contacting sheet is formed from a substantially water-impermeable plastic film material and more preferably the plastic film material is substantially

non-swelling in water or wound fluid.

[0013] Preferably, the wound contacting sheet is bonded to the layer of water-swellaible absorbent material over at least part of its area, for example by adhesive or heat bonding. For example, a margin of the wound contacting sheet may be bonded to a margin of the absorbent layer. Preferably, the wound contacting sheet is bonded to the absorbent layer over substantially the whole wound contacting area of the dressing.

[0014] Preferably, the layer of water-swellaible absorbent material is from 1.0 mm to 10 mm thick in the unswollen state. Preferably, the layer of water-swellaible absorbent material expands by at least 25% in thickness when it is saturated with water. More preferably, it expands by at least 50% in thickness when it is saturated with water, and most preferably it swells by about 85% or more when it is saturated with water.

[0015] The water-swellaible absorbent material is a polyurethane polymer foam.

[0016] Particularly preferred are the polyurethane foams that are commercially available from Johnson & Johnson Medical, Inc. under the Registered Trade Mark TIELLE. The preparation and properties of such polyurethane foams are described in detail in European patent applications EP-A-0541391 and EP-A-0541390. Briefly, the polyurethane foam is made by mixing 1 part by weight of an isocyanate-capped prepolymer having from 0.5 to 1.2 meq NCO groups/g with from 0.4 to 1.0 parts by weight of water in the presence of from 0.05 to 0.4 parts by weight of a C1 to C3 monohydric alcohol, and then drying the product. The monohydric alcohol is preferably methanol, and the isocyanate-capped prepolymer is preferably an isocyanate-capped ethyleneoxy/propyleneoxy copolymer.

[0017] The wound dressings according to the present invention further comprise a backing layer located on the side of the absorbent layer opposite to the wound contacting layer. The backing layer helps to confine the absorbent layer, to ensure that swelling of the absorbent layer results in bulging of the wound contacting layer to open the slits in the wound contacting sheet. The backing layer is substantially liquid-impermeable to prevent leakage of wound exudate from the absorbent layer into clothes, bedclothes etc. For example, the backing layer may be formed from water vapour and gas-permeable, water and microbe-impermeable polyurethane film of the kind conventionally used for adhesive wound dressings. The backing layer is preferably bonded to the absorbent layer by heat or adhesive. Preferably, a layer of medical grade pressure-sensitive adhesive extends over the whole inner surface of the backing layer to bond the backing layer to the water-swellaible absorbent layer. The adhesive also modifies the air- and water-permeability of the backing layer to give it the desired characteristics.

[0018] Preferably, the backing layer extends beyond the edges of the absorbent layer and of the wound contacting sheet to form a margin around the absorbent layer

and the wound contacting sheet, and adhesive is provided on the margin for securing the margin of the backing layer to the skin of the patient around a wound. Such dressings are commonly known as island dressings, because the absorbent layer is formed as an island on the adhesive-coated surface of a larger backing layer. The same layer of adhesive preferably extends over the whole inner surface of the backing layer, for the reasons given above. Preferably, the wound contacting sheet and any adhesive-coated margin of the backing layer are covered before use by a cover sheet that is removed and discarded before use. The cover sheet may comprise a plastics film or release-coated paper, as is conventional for adhesive island-type dressings. The wound dressing is preferably sterile packaged, and is preferably sterilized by gamma-irradiation.

[0019] It will be appreciated that the use of the term "wound contacting sheet" here and elsewhere in the specification, does not exclude the possibility that dressings according to the present invention may have a further layer between the wound contacting sheet as here-in defined and the wound surface. For example, there may be a further layer of gel, or a wound contacting hydrogel net to assist removal of the wound dressing from the wound surface and provide a more wound-friendly contacting surface.

[0020] It is envisaged that the wound dressings according to the present invention will be packaged in conventional fashion in sterile packaging, and sterilized in conventional fashion, such as by gamma-irradiation.

[0021] Specific embodiments of the wound dressing according to the present invention will now be described further, by way of example, with reference to the accompanying drawings, in which:-

Figure 1 shows a perspective view of a wound dressing according to the present invention immediately before application to an exuding wound; and Figure 2 shows the wound dressing of Figure 1 following application to an exuding wound, showing the effect of exudate absorption and swelling on the structure of the wound dressing.

[0022] Referring to Figure 1, the wound dressing comprises a backing layer 2 formed from a water-repellent or water-impermeable elastomer. A particularly suitable material is Medifix 4005 (Registered Trade Mark) supplied by the Medifix company which is a polyurethane foam of blocked toluene diisocyanate nature, and is predominantly closed cell.

[0023] The wound dressing further comprises an absorbent layer 3 approximately 1.5mm thick of a water-swellaible polyurethane formed from a prepolymer as described in EP-A-0541391. The prepolymer is preferably an isocyanate-capped polyether, such as ethyleneoxy/propyleneoxy copolymer. A particularly suitable prepolymer is available under the Registered Trade Mark HYPOL supplied by Hampshire Chemicals.

[0024] The wound dressing further comprises wound contacting sheet 4 having a plurality of linear, parallel slits 5 therein. The sheet 4 is bonded to the surface of the absorbent layer either by a layer of medical grade adhesive or by a suitable heat laminating process. The wound contacting sheet is formed from a medical grade elastomer. A particularly suitable material is a polyurethane film. The slits are preferably die-cut, and are preferably 2mm to 20mm long.

[0025] The backing layer 2 extends beyond the edges of the absorbent layer 3 and wound contacting sheet 4 to form a circumferential margin 6 approximately 1 cm wide, which is coated with a layer of pressure-sensitive adhesive of the kind conventionally used in the wound dressing art. Prior to use, the adhesive is protected by release-coated paper sheets (not shown) in conventional fashion.

[0026] In use, the dressing 1 is applied to an exuding wound. The wound exudate flows through the wound contacting sheet 4 into the absorbent layer 3, where it is trapped and causes the polyurethane polymer to swell. This results in the situation shown in Figure 2, where it can be seen that swelling of the absorbent layer has caused the wound contacting sheet 4 to bulge outwardly, opening the slits 5 to ovoid shapes that allow passage of high flow rates of exudate into the absorbent layer. This process is, of course, reversible when the rate of exudate production falls, causing the absorbent layer to dry out due to evaporation of water vapour through the semipermeable backing sheet 2.

[0027] It can thus be seen that this absorbent wound dressing can handle a wide range of exudate flow rates, avoids shedding of absorbent material into the wound bed, and prevents excessive drying out of the wound surface.

[0028] The above embodiment has been described by way of example only. Many other embodiments falling within the scope of the accompanying claims will be apparent to the skilled reader.

Claims

1. A wound dressing (1) comprising a wound contacting sheet (4) laminated to one side of an absorbent layer (3) of water-swella-
ble absorbent material, a liquid water-impermeable backing layer (2) is laminated to the other side of the absorbent layer (3), wherein the wound contacting sheet is provided with one or more slits (5) therein, whereby swelling of the absorbent layer (3) due to absorption of wound exudate causes the wound contacting sheet (4) to bulge, thereby opening up the slits to increase the liquid permeability of the wound contacting sheet, **characterised in that** the absorbent material (3) is a polyurethane polymer foam such that the swelling of the absorbent layer (3) is reversible.

2. A wound dressing according to claim 1, wherein a plurality of said slits (5) are provided in the wound contacting sheet (4).
3. A wound dressing according to claim 2, wherein said plurality of slits (5) are substantially linear and parallel.
4. A wound dressing according to any preceding claim, wherein the wound contacting sheet (4) is bonded to the layer of water-swella-
ble absorbent material (3) over at least part of its area.
5. A wound dressing according to claim 4, wherein the wound contacting sheet (4) is bonded to the layer of water-swella-
ble absorbent material (3) over substantially the whole wound contacting area of the dressing.
6. A wound dressing according to any preceding claim, wherein the layer of water-swella-
ble absorbent material (3) is from 1.0 mm to 10 mm thick in the unswollen state.
7. A wound dressing according to any preceding claim, wherein the backing layer (2) extends beyond the absorbent layer (3) and the wound contacting sheet (4) to form a margin (6) around the absorbent layer (3) and the wound contacting sheet (4), and adhesive is provided on said margin (6) for securing said margin (6) to the skin of a patient around a wound.
8. A wound dressing according to any preceding claim which is sterile packaged.

Patentansprüche

1. Wundpflaster umfassend eine Wundberührungsschicht (4), die auf eine Seite einer absorbierenden Schicht (3) aus einem durch Wasser anschwellbaren absorbierenden Material aufgetragen ist, wobei eine für Flüssigkeit bzw. Wasser undurchlässige Trägerschicht (2) auf die andere Seite der absorbierenden Schicht (3) aufgetragen ist und die Wundberührungsschicht einen oder mehrere Schlitz(e) (5) aufweist, wodurch ein Anschwellen der absorbierenden Schicht (3) durch Absorption von Wundexsudat ein Ausbauchen der Wundberührungsschicht hervorruft, wodurch die Schlitz(e) (5) geöffnet werden, um die Flüssigkeitspermeabilität der Wundberührungsschicht zu erhöhen, **dadurch gekennzeichnet, daß** das absorbierende Material (3) ein Polyurethanpolymerschäum ist, so daß das Anschwellen der absorbierenden Schicht (3) reversibel ist.

2. Wundpflaster nach Anspruch 1, **dadurch gekennzeichnet, daß** eine Vielzahl von Schlitzten (5) in der Wundberührungsschicht (4) angeordnet sind.

3. Wundpflaster nach Anspruch 2, **dadurch gekennzeichnet, daß** die Vielzahl von Schlitzten (5) im wesentlichen linear und parallel sind.

4. Wundpflaster nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, daß** die Wundberührungsschicht (4) mit der Schicht des durch Wasser anschwellbaren, absorbierenden Materials (3) über mindestens einen Teil seiner Fläche verbunden ist.

5. Wundpflaster nach Anspruch 4, **dadurch gekennzeichnet, daß** die Wundberührungsschicht (4) im wesentlichen über die gesamte Wundberührungsfläche des Pflasters mit der Schicht des durch Wasser anschwellbaren, absorbierenden Materials (3) verbunden ist.

6. Wundpflaster nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, daß** die Schicht des durch Wasser anschwellbaren, absorbierenden Materials (3) im nicht angeschwollenen Zustand 1 bis 10 mm dick ist.

7. Wundpflaster nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, daß** die Trägerschicht (2) sich über die absorbierende Schicht (3) und die Wundberührungsschicht (4) hinaus erstreckt, um einen Rand (6) um die absorbierende Schicht (3) und die Wundberührungsschicht (4) zu bilden, wobei ein Klebemittel auf dem Rand (6) aufgetragen ist, um den Rand (6) auf der Haut eines Patienten um eine Wunde herum zu sichern.

8. Wundpflaster nach einem der vorangehenden Ansprüche, **dadurch gekennzeichnet, daß** es steril verpackt ist.

Revendications

1. Pansement (1) comprenant une feuille (4) venant en contact avec la blessure, qui est appliquée sur une face d'une couche absorbante (3) d'un matériau absorbant gonflant sous l'effet d'absorption d'eau, une couche arrière (2) imperméable à un liquide ou à l'eau, qui est appliquée sur l'autre face de la couche absorbante (3), et dans lequel la feuille en contact avec la blessure comporte une ou plusieurs fentes (5), ce qui a pour effet que le gonflement de la couche absorbante (3) sous l'effet de l'absorption de l'exsudat de la blessure provoque un renflement de la feuille (4) en contact avec la blessure, ce qui a pour effet de maintenir ouvertes

les fentes de manière à augmenter la perméabilité de la feuille en contact avec la blessure, vis-à-vis d'un liquide, **caractérisé en ce que** le matériau absorbant (3) est une mousse polymère de polyuréthane telle que le gonflement de la couche absorbante (3) est réversible.

2. Pansement selon la revendication 1, dans lequel une pluralité desdites fentes (5) sont prévues dans la feuille (4) en contact avec la blessure.

3. Pansement selon la revendication 2, dans lequel ladite pluralité de fentes (5) sont essentiellement linéaires et parallèles.

4. Pansement selon l'une quelconque des revendications précédentes, dans lequel la feuille (4) en contact avec la blessure est fixée à la couche du matériau absorbant (3) apte à gonfler sous l'effet d'absorption d'eau, sur au moins une partie de sa surface.

5. Pansement selon la revendication 4, dans lequel la feuille (4) en contact avec la blessure est fixée à la couche du matériau absorbant (3) apte à gonfler sous l'effet d'absorption d'eau, essentiellement sur toute la surface du pansement en contact avec la blessure.

6. Pansement selon l'une quelconque des revendications précédentes, dans lequel la couche du matériau absorbant (3) apte à gonfler sous l'effet d'absorption d'eau, possède une épaisseur comprise entre 1,0 mm et 10 mm à l'état non gonflé.

7. Pansement selon l'une quelconque des revendications précédentes, dans lequel la couche arrière (2) s'étend au-delà de la couche absorbante (3) et de la feuille (4) en contact avec la blessure de manière à former un bord (6) autour de la couche absorbante (3) et de la feuille (4) en contact avec la blessure, et un adhésif est prévu sur ledit bord (6) pour fixer ledit bord (6) sur la peau d'un patient autour d'une blessure.

8. Pansement selon l'une quelconque des revendications précédentes, qui est emballé de façon stérile.

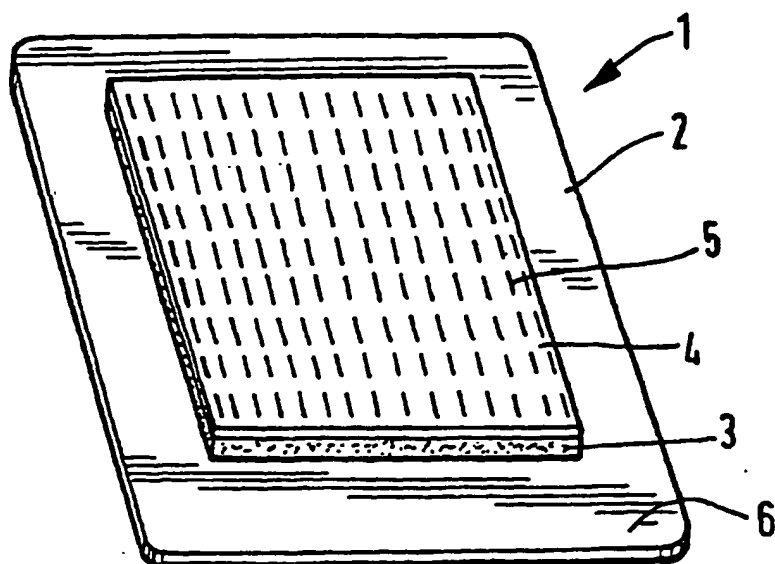


Fig.1

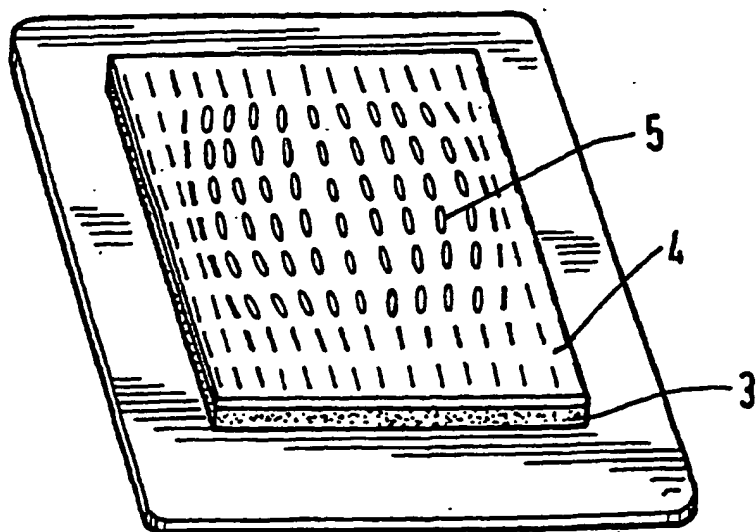


Fig.2